August 15, 2025

Ms. Meredyth Andrus
Health Care Division, Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue NW
Washington, DC 20580

Dear Ms. Andrus:

On behalf of the Council for Innovation Promotion (C4IP), we write to submit comments in connection with the Department of Justice and Federal Trade Commission's recent listening sessions on "lowering Americans' drug prices through competition."

C4IP is a bipartisan coalition dedicated to promoting strong and effective intellectual property (IP) rights, driving innovation, boosting economic competitiveness, and improving lives everywhere.

C4IP is chaired by two former Under Secretaries for Intellectual Property and U.S. Patent and Trademark Office (USPTO) Directors: Andrei Iancu, who served in the first Trump administration, and David Kappos, who served in the Obama administration. Our board includes two retired judges from the Court of Appeals for the Federal Circuit: former Chief Judge Paul Michel, who was appointed by President Reagan, and former Judge Kathleen O'Malley, who was appointed by President Obama. Our board also includes two distinguished public servants: Gary Locke, former Governor of Washington, U.S. Secretary of Commerce, and U.S. Ambassador to China under President Obama; and Lamar Smith, former U.S. Representative for Texas's 21st congressional district and Chairman of the House Judiciary Committee.

Our organization feels compelled to submit comments in response to the recent listening sessions because we are concerned that the sessions have amplified certain false narratives about the U.S. intellectual property system and the role of IP rights in drug development. If these misleading narratives form the basis for new policy interventions that undermine patents, it would only serve to undermine the system that allows for progress in the life sciences. Further, the repercussions would extend beyond medicines to other areas of innovation that the patent system incentivizes, jeopardizing America's status as the world leader in innovation. As Coke Stewart,

Acting Under Secretary of Commerce for Intellectual Property and Deputy Director of the USPTO, noted at the beginning of her remarks during the August 4 session, intellectual property rights have been constitutionally protected since America's founding, providing the foundation for this country's prosperity and leadership.

Yet, although Director Stewart and certain other panelists provided informed perspectives on how the patent system functions to promote innovation, they were outnumbered by voices critical of IP, often based on false or misleading narratives (as explained further below). We have submitted the comments below with the aim of encouraging a more robust and well-rounded dialogue on these important issues. C4IP respectfully urges the FTC and DOJ to consider our comments and use them as a constructive resource as any further work on these issues occurs.

Patent Quality Is High in the United States, Providing a Necessary Foundation for Medical and Other Types of Innovation

Throughout the listening sessions, some panelists claimed that junk or "low-quality" patents are often granted under the U.S. patent system. This claim is false. A 2024 analysis by the nonpartisan Sunwater Institute found that the USPTO grants invalid patents at a rate of less than 10% -- comparing favorably to other major patent offices worldwide. The reliability of the U.S. patent system gives innovators the certainty needed to pursue long-term, high-risk R&D, such as in the complex field of medicine.

The Sunwater Institute's findings discredit the claim that the United States is overflowing with low-quality patents. In fact, they demonstrate the opposite: that the USPTO overwhelmingly grants valid patent claims that meet the statutory requirements of being useful, novel, and non-obvious.

The Sunwater Institute report further outlines that valid patent claims are actually more likely to be unfairly denied a patent than to be wrongfully issued one.

Despite this, some panelists questioned the USPTO's application of the standard for novelty and non-obviousness, two critical aspects of patent quality and validity. In particular, during discussions of "follow-on innovation" -- the process of updating and improving existing medications and other products to best serve user needs -- several participants alleged that these updated products are largely undeserving of patent protection. But in reality, the improvements are not simply minor changes, despite suggestions from panelists Sneha Dave, Founder & Executive Director of

Generation Patient, and Sarah D'Orsie, SVP of Global Government Affairs and Policy at Fresenius Kabi Biopharmaceuticals, during the June 30 and July 24 sessions, respectively. Patents on improvements must meet the same statutory requirements as any other innovation, and moreover, their contribution to innovation overall should not be dismissed as somehow insignificant. These advances reflect deeper exploration and refinement, which frequently translates to real-life improvements for patients, and set the stage for further scientific inquiry and even greater breakthroughs.

A recent report from the Information Technology and Innovation Foundation (ITIF) found that updated versions of medications can increase adherence, reduce side effects, and make administration easier. These changes not only improve patient quality of life, but they can also reduce healthcare costs. Studies show that improved medication adherence lowers healthcare costs by decreasing the likelihood of medical complications and hospital stays.

Insulin is a clear example of how improvements to existing treatments can deliver lasting benefits. Before the discovery of insulin, the average person with type 1 diabetes lived less than three years. The first treatments used insulin isolated from cattle and pigs, and while revolutionary, some patients had allergic reactions because of the source. Genetically engineered human versions later helped address that problem. In sum, over the past century, patent-supported innovation has continued to produce new and more effective or tolerated versions, from this biosynthetic human insulin to ultra-long and rapid-acting versions, improving blood sugar control, reducing hypoglycemia risk, and extending life expectancy significantly.

Further, updated iterations of medications are not simple pursuits for manufacturers. A 2023 analysis of drugs selected for Medicare price negotiation found that the majority of research and development costs are incurred after a drug is approved by the Food and Drug Administration (FDA) -- demonstrating that post-approval R&D is significant and helps advance medical knowledge.

In other words, despite the claims asserted during the listening sessions, evidence shows that developing updated versions of existing treatments is both time- and resource-intensive and improves patient health outcomes while reducing costs for healthcare systems. Limiting patent protection for these novel innovations would not lower drug costs. Instead, it would harm patients, burden healthcare systems, and destroy incentives to seek new transformative technologies.

There Is No Evidence that the Number of Patents Covering a Product Affects the Timing of Generic Entry

A number of unfounded allegations about the patent system were made throughout the sessions -- allegations that we refer to as "patent myths." One such myth is the idea that if too many patents cover a given drug treatment, entry of generic versions of that drug will be unfairly delayed.[1] That unsubstantiated assertion is contradicted by fact-based studies showing that the period of market exclusivity a branded drug actually enjoys before generic competition is less than the 20-year maximum term of a patent.

In particular, a 2024 USPTO study directly refuted claims that the number of patents on a drug extends exclusivity. Reviewing a broad cohort of products, the agency found no correlation between the number of Orange Book patents on a product and the timing of generic market entry. In fact, the average exclusivity period observed was significantly shorter than the statutory 20-year patent term by almost a decade. Additional studies and reports going back decades also support this data.

These points were further reinforced by Senator Thom Tillis's (R-NC) IP advisor, Peter-Anthony Pappas, in the August 4 session. As Hans Sauer of the Biotechnology Innovation Organization further explained, filing multiple patents on one product is a common practice across most industries, not just the pharmaceutical sector. When a high-tech product is protected by multiple patents, it is because those patents are necessary to encompass the product's complexity -- not because it helps the manufacturer undermine competition.

D'Orsie further alleged that due to "patent thickets," products in the United States are protected by a higher number of patents than products in other countries. But this disregards differences in patent systems worldwide and obscures the fact that patent count alone has no bearing on generic market entry.

While evidence contradicts the alleged premise of "patent thickets," several legislative proposals nonetheless seek to resolve this nonexistent problem.

[1] This point was made by Sneha Dave of Generation Patient, Stephen Schondelmeyer of the University of Minnesota, and Alex Brill of the American Enterprise Institute at the June 30 session and by Sarah D'Orsie of Fresenius Kabi Biopharmaceuticals at the July 24 session.

For example, the **Affordable Prescriptions for Patients Act (S. 1041)** takes aim at the so-called "patent thickets" by limiting the number of patents a drug manufacturer can defend in court. It would restrict companies from defending certain patents filed more than four years after a drug initially secured FDA approval. This legislation would therefore undermine the ability of inventors to protect legitimate and updated versions of a product, discouraging investment in improvements. By conditioning patent enforceability on timing and quantity rather than merit, the bill risks setting a troubling precedent that could stifle medical progress. A more detailed explanation of C4IP's concerns about this bill is available here.

Furthermore, the **Eliminating Thickets to Increase Competition (ETHIC) Act (S. 2276)** would prohibit patent holders in the pharmaceutical sector from asserting more than one patent out of a certain defined group of patents in infringement cases in a separate attempt to address so-called "patent thickets." However, it is critical to remember that multiple patents are often required to fully encompass the range of innovations found in complex products, particularly in cutting-edge fields like medicine and technology. Rather than promote equitable innovation, this bill would simply strip companies of the rights needed to attract investment, build partnerships, and bring new technologies to market.

Improved Versions of Older Products Should Be Encouraged, Not Penalized

Several panelists also complained about the alleged practice of so-called "product hopping."[2] "Product hopping" is a misleading term that implies innovators deliberately hinder competition by making minor changes to existing products while discontinuing earlier versions.

In fact, developing safer and more effective versions of products while discontinuing older versions of products is a common-sense practice and is widely accepted in other industries, from cars to smartphones. Criticizing the pharmaceutical industry for this well-intended and necessary practice only serves to disincentivize continued medical innovation and decrease quality of life for patients.

[2] This point was made by Alex Brill and Michael Carrier of Rutgers Law School at the June 30 session, as well as Nic Pottebaum, a counsel to Senator Chuck Grassley (R-IA), and Franci Rooney Becker, chief counsel to Senator John Cornyn (R-TX), during the August 4 session.

The **Drug Competition Enhancement Act (S. 1040)** aims to address this alleged issue of "product hopping." But rather than fostering innovation, the bill risks mislabeling scientific progress as wrongdoing -- undermining advancements in treatment and threatening the system responsible for continued medical breakthroughs. A more detailed explanation of C4IP's concerns about this bill is available here.

Existing Legal Mechanisms Ensure Robust Generic Competition For Patent-Protected Drugs, But Patent Protection Alone Does Not Govern Generic Entry

The law already provides two streamlined mechanisms for allowing would-be generic competitors to challenge the patents protecting approved drug products: the Hatch-Waxman Act, which covers small-molecule drugs, and the Biologic Price Competition and Innovation Act, which covers complex biologics. The efficacy of these mechanisms is apparent from the fact that nine in 10 prescriptions filled in the United States are manufactured by generic manufacturers.

These numbers alone dispel the claim made by some panelists, such as Stephen Schondelmeyer, a representative of the University of Minnesota, that the Hatch-Waxman Act has led to decreased competition for generics in the United States. In fact, the opposite is true.

Moreover, as one of the panelists critical of the patent system conceded, the presence of patents alone does not determine whether a generic version will enter the market. This panelist, Brill, remarked that 90% of biologics that will lose patent protection within the next decade are not expected to have biosimilar competition at all. As the source for that statistic (a report from the Center for Biosimilars) further explained, the main factors limiting biosimilar development do not include the patent system, but rather other factors such as cost and regulatory barriers.

Mandating Unnecessary Coordination Between the USPTO and FDA Would Not Affect Patent Quality, but Would Harm Innovators

In recent years, some lawmakers have advanced proposals to increase coordination between the USPTO and the Food and Drug Administration (FDA) in the review of pharmaceutical patents. Proponents argue such measures could streamline oversight and improve patent quality. However, in practice, these initiatives risk

adding bureaucracy to two already complex regulatory systems -- without clear evidence that they would improve outcomes.

Two bills currently before Congress respond to this supposed concern, including the **Interagency Patent Coordination and Improvement Act (S. 1097)**, which would create an interagency task force to facilitate information sharing between the USPTO and the FDA, and require the USPTO to report to Congress on both the frequency and use of such information in patent examinations. This bill was discussed by a representative for Senator Chuck Grassley (R-IA) during the August 4 session.

The other bill, the **Medication Affordability and Patent Integrity Act (MAPIA) (S. 2780)**, would require life science innovators to disclose extensive, often confidential, information related to the FDA drug approval process to the USPTO and certify that their submissions to the USPTO and FDA are consistent. Its supporters claim that this would enhance transparency in the pharmaceutical industry.[3] This bill was discussed by a policy advisor to Representative Diana Harshbarger (R-TN).

Both of these bills are based on the unfounded premise that there is systematic abuse under which pharmaceutical companies make representations to the USPTO when applying for patent protection that are contradicted by statements they make to the FDA when applying for drug approval. But existing law already provides serious and significant consequences for instances of fraud. Innovators can have their patents rendered unenforceable if found to have made false statements to the USPTO, which imposes a duty of candor on patent applicants. This authority has proven effective at addressing isolated instances of abuse, and despite incentives for generic companies to identify such abuse during patent litigation, actual examples are exceedingly few and do not point to a systematic problem.

Yet both of these bills would impose significant costs on the USPTO, FDA, and patent applicants as if a systematic problem exists. There is a reason why there is not already automatic duplication of submissions to the USPTO and FDA -- the information submitted to the FDA often would have no relation to the invention that is the subject of a patent application. Relatedly, the FDA staff are not -- and

[3] During the August 4 session, a policy advisor to Representative Diana Harshbarger (R-TN) stated that MAPIA would save American taxpayers $100 million over a decade, citing the Congressional Budget Office as the source. However, this figure does not appear to be publicly accessible or verifiable, raising concerns about its credibility and transparency.

have no reason to be -- experts in the patent application process and vice versa. This means that the FDA does not have the expertise to assist in the patent examination process, nor does it even have the background to know what part of the voluminous documentation it receives would be relevant to any given patent application.

Information about human safety, for example, may have no bearing on a patent application for new methods of creating a class of potential active ingredients. Requiring duplication of submissions would result in putting hundreds or thousands of pages of information before a patent examiner that they are expected to consider. This is a poor use of government resources; forcing the USPTO to review this volume of irrelevant information could exacerbate delays in the patent application process, ultimately meaning that novel treatments take longer to reach patients.

In addition, these bills could result in sensitive data, typically kept confidential by the FDA, being shared with the USPTO, which generally makes all information related to the examination of a patent application public. This would be a significant and unwarranted harm inflicted on innovator companies, potentially opening the doors to other would-be competitors, including state actors such as China, to take advantage of this newly free resource to bolster their own efforts to out-innovate the United States in biotech and other critical fields.

In sum, both of these bills would needlessly risk an overhaul of a robust, functioning IP system -- creating more bureaucratic hurdles, risk to trade secrets, and legal vulnerabilities for innovative individuals and companies -- without substantiated justification. A more detailed explanation of C4IP's concerns about the Interagency Patent Coordination and Improvement Act can be found here and here, and concerns about MAPIA can be found here and here.

Maintaining America's Lead in Medical Innovation Requires a Strong Patent System

As Sen. Tillis's IP advisor pointed out during the August 4 panel, the United States is a world leader in pharmaceutical innovation. But our leadership is currently under threat.

China is quickly approaching, and in some cases even surpassing, the United States in medical innovation and clinical trial investment. As China grows its lead in the majority of critical and emerging technologies, according to recent reports, it is more

crucial than ever for the United States to uphold the IP system that drives innovation in pharmaceuticals and other economically and strategically vital sectors.

The incentives created by strong patent protections drive over $100 billion in annual industry investment in groundbreaking cures and medications. Overhauling the well-balanced U.S. patent system without reason could devastate the development of medical treatments and jeopardize American patients' health and safety, as well as the nation's broader national security.

Rather than undermining these incentives in pursuit of increased innovation, the United States should push for other countries to pay their fair share for benefiting from American-financed breakthroughs. Many developed countries continually benefit from U.S.-financed pharmaceutical innovation while keeping their own drug prices artificially low, thus limiting investment in medical innovation. This dynamic places an outsized share of the global burden for funding medical innovation on American patients and the U.S. health care system.

By ensuring fair treatment from our global trade partners, the United States could reduce obstacles to lower drug prices without putting future medical breakthroughs at risk.

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Sen. Tillis's advisor also stated that "we would not be having a conversation today regarding drug affordability and accessibility if it were not for the U.S. patent system, which encouraged and enabled these drugs to exist in the first place. There is a reason why the world looks to our country when it comes to strong patent rights."

Scapegoating patents for broader affordability challenges is both misguided and harmful. As Sen. Tillis's advisor emphasized, it is critical to closely scrutinize data attacking the U.S. intellectual property system, as many widely spread claims by anti-innovation organizations have been disproven.

Patents are not barriers to competition; they are the mechanism that transforms early discoveries into lifesaving therapies. By securing inventors' rights, patents attract investment, enable clinical trials, and support large-scale manufacturing. Without reliable IP rights, investment in breakthrough cancer therapies, gene

editing technologies, and pandemic preparedness tools would be severely constrained, if not abandoned.

Patients, innovators, and patent holders are fortunate to have leadership like that of Senator Tillis and Acting Director Stewart -- as well as champions who were not featured during the listening sessions, like Senator Chris Coons (D-DE). As Director Stewart emphasized, if the United States is to remain the global leader in innovation, it must promote the IP incentives that allow our high-tech industries to grow.

As the FTC and DOJ evaluate next steps, we urge caution against measures that would weaken the patent system under the false premise of improving affordability. America leads the world in medical innovation because our policies reward risk-taking and protect invention. Dismantling those incentives would inflict lasting harm on researchers, investors, and -- most importantly -- patients who depend on scientific progress.

C4IP appreciates the opportunity to submit these comments and stands ready to assist the FTC and DOJ in advancing policies that strengthen America's innovation economy.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)